Complete Summary

GUIDELINE TITLE

Guidelines for the management of acute coronary syndromes 2006.

BIBLIOGRAPHIC SOURCE(S)

Acute Coronary Syndrome Guidelines Working Group. Guidelines for the management of acute coronary syndromes 2006. Med J Aust 2006 Apr 17;184(8 Suppl):S1-32. [105 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Acute coronary syndrome (ACS), including both ST-segment-elevation myocardial infarction and non-ST-segment-elevation ACS

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Cardiology
Emergency Medicine
Internal Medicine

INTENDED USERS

Emergency Medical Technicians/Paramedics
Physicians

GUIDELINE OBJECTIVE(S)

- To incorporate contemporary information on the diagnosis and management of acute coronary syndrome into a set of recommendations that defines the boundaries of highest quality care
- To expand on previous guidelines by consolidating recommendations for the management of ST-segment-elevation myocardial infarction (STEMI), non-ST-segment-elevation myocardial infarction, and unstable angina, as well as incorporating the newer developments that have arisen since the previous guidelines

TARGET POPULATION

Patients with acute coronary syndromes (ACS), which includes a broad spectrum of clinical presentations, spanning ST-segment-elevation myocardial infarction, through to an accelerated pattern of angina without evidence of myonecrosis

INTERVENTIONS AND PRACTICES CONSIDERED

1. Establish adequate systems of care
2. Establish initial working diagnosis
3. Encourage patients to seek help promptly including the use of emergency medical services

4. Provide access to defibrillator
5. Manage chest pain with aspirin, oxygen, and glyceryl trinitrate and intravenous morphine, as required
6. Provide advanced warning to medical facilities
7. Electrocardiogram (ECG) en route to medical facility
8. Prehospital treatment (including fibrinolysis as appropriate)
9. Investigations including ECG, cardiac marker levels, and provocative testing (e.g., stress test) before discharge
10. Management of patients with ST-segment-elevation myocardial infarction (STEMI) with reperfusion (percutaneous coronary intervention [PCI] or fibrinolysis), adjuvant therapy in association with reperfusion (aspirin and clopidogrel, abciximab), and transfer of patients after STEMI to a tertiary cardiac centre
11. Management of patients with non-ST-segment-elevation acute coronary syndromes using risk stratification, aspirin, aggressive medical management (aspirin, clopidogrel, unfractionated heparin or subcutaneous enoxaparin, intravenous triofiban or eptifibatide, and a beta blocker), coronary angiography, revascularization, accelerated diagnostic evaluation, discharge (as appropriate)
12. Long-term management including medication regimen (anti-platelet agents, beta-blocker, angiotensin-converting enzyme inhibitor, statin), implantable cardiac defibrillators, lifestyle education, referral for prevention and cardiac rehabilitation services, written action plans, and assessment of depression and social support

MAJOR OUTCOMES CONSIDERED

Rates of deaths, myocardial infarctions, reinfarctions, and strokes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

II: Evidence obtained from at least one properly designed randomised controlled trial

III-1: Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)

III-2: Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies, or interrupted time series without a control group

III-3: Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series with a parallel control group

IV: Evidence obtained from case series, either post-test or pre-test and post-test

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines were developed on a foundation of evidence-based criteria, using a consensus approach. They are the outcome of a review of recent evidence, representations of key expert groups and stakeholders, and many meetings of writing group members during 2004 and 2005.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

A. Rich body of high-quality randomized controlled trial (RCT) data (evidence level I)
B. Limited body of RCT data or high-quality non-RCT data (evidence level II, III-1, III-2)
C. Limited evidence (evidence level III-3, IV)

D. No evidence available – panel consensus judgment

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Broad consultation was undertaken to finalise the content of these guidelines, and they have been endorsed by:

- Australasian College for Emergency Medicine
- Australian Cardiac Rehabilitation Association
- Australian Indigenous Doctors' Association
- Australian Resuscitation Council
- Council of Ambulance Authorities
- Council of Remote Area Nurses of Australia Inc
- Internal Medicine Society of Australia and New Zealand
- Kidney Health Australia
- National Aboriginal Community Controlled Health Organisation
- Royal Australian College of General Practitioners
- Royal College of Nursing Australia

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse: The recommendations that follow are from the guideline's "Summary of Key Recommendations"; detailed graded recommendations can be found in the original guideline document.

Systems of Care for Patients with Acute Coronary Syndromes

- Effective systems of care are required to deliver optimal care for patients with acute coronary syndromes (ACS), particularly in rural and remote areas.
- Systems of care should be regionally based, and have formal links with specialist centres for consultation and acute interhospital transfer.
- Systems should include appropriate monitoring, feedback, and quality improvement components.
- Clinical decisions about care and transfer should take into account patients' cultural and personal beliefs and wishes.

New Acute Coronary Syndrome Terminology and Implications for Diagnosis

- It is important to establish an initial working diagnosis to guide clinical decision making.
- New definitions of myocardial infarction, based heavily on the presence of cardiac biomarkers, have implications for coding and epidemiological studies. However, clinically they do not influence the indications for ongoing prevention therapies.
- Use of the ACS Dataset (part of the National Health Data Dictionary) can facilitate the collection of data relating to the presentation and management of ACS that can be compared and collated within and between health care providers.

Acute Management of Chest Pain

- People experiencing symptoms of an ACS should seek help promptly and activate emergency medical services.
- The most important initial need is access to a defibrillator to avoid early cardiac death resulting from reversible arrhythmias.
- Aspirin should be given early (i.e., by emergency or ambulance personnel) unless already taken or contraindicated.
- Oxygen should be given, as well as glyceryl trinitrate and intravenous morphine as required.
- As a minimum, medical facilities receiving patients should be given warning of incoming patients in whom there is a high suspicion of an ACS—particularly ST-segment-elevation myocardial infarction (STEMI)—or whose condition is unstable.
- Where appropriate, a 12-lead electrocardiogram (ECG) should be taken en route and transmitted to a medical facility.
- Where formal protocols are in place, prehospital treatment (including fibrinolysis in appropriate cases) should be facilitated.

Investigations

- The ECG is the sole test required to select patients for emergency reperfusion (fibrinolytic therapy or direct percutaneous coronary intervention [PCI]).
- Patients with STEMI who present within 12 hours of the onset of ischaemic symptoms should have a reperfusion strategy implemented promptly.
- Patients with a suspected ACS without ST-segment elevation on ECG should undergo further observation and investigation to rule out other diagnoses, enable risk stratification, and determine the most appropriate treatment strategy.
- Patients whose ECG and cardiac marker levels are normal after a suitable period of observation should, where practicable, undergo provocative testing (e.g., stress test) before discharge.

Management of Patients with ST-Segment-Elevation Myocardial Infarction

Adjuvant Therapy in Association with Reperfusion

- All patients undergoing reperfusion therapy for STEMI (PCI or fibrinolysis) should be given aspirin and clopidogrel unless these are contraindicated.

- Antithrombin therapy should be given in combination with PCI or fibrinolytic therapy with fibrin-specific fibrinolytic agents, but antithrombin therapy in conjunction with streptokinase is optional.
- It is reasonable to use abciximab with primary PCI, but glycoprotein (GP) IIb/IIIa inhibitors should generally be avoided with full or reduced doses of fibrinolytic therapy.

Choice of Reperfusion Strategy

- Time delay (both to first medical contact and potential PCI or fibrinolytic therapy) plays a major role in determining best management of STEMI.
- In general, PCI is the treatment of choice, providing it can be performed promptly by a qualified interventional cardiologist in an appropriate facility.
- In general, the maximum acceptable delay from presentation to balloon inflation is:
    - 60 minutes if a patient presents within 1 hour of symptom onset; or
    - 90 minutes if a patient presents later

  Note: for patients who present late (between 3 and 12 hours after symptom onset) to a facility without PCI capability, it is appropriate to consider transfer for primary PCI if balloon inflation can be achieved within 2 hours (including transport time).

- All PCI facilities should be able to perform angioplasty within 90 minutes of patient presentation.
- Fibrinolysis should be considered early if PCI is not readily available, particularly in rural and remote areas.
- When there are major delays to hospitalisation (i.e., more than 30 minutes), prehospital fibrinolysis should be considered.
- Reperfusion is not routinely recommended in patients who present more than 12 hours after symptom onset and who are asymptomatic and haemodynamically stable.

Choice of Fibrinolytic Agent

- Second-generation fibrin-specific fibrinolytic agents that are available as a bolus (i.e., reteplase, tenecteplase) are the fibrinolytics of choice.
- These agents should be available at all centres where fibrinolysis may be required.
- Streptokinase is an inappropriate choice in Aboriginal and Torres Strait Islander patients, or in patients with previous exposure to the drug.

Transfer after STEMI

- Patients who have had STEMI should be considered for early transfer to a tertiary cardiac centre with PCI facilities and links to cardiac surgical facilities.
- If immediate transfer is not possible, patients should be transferred or referred as soon as is practicable for assessment of need for revascularisation (through PCI or coronary artery bypass grafting).

Management of Patients with Non-ST-Segment-Elevation Acute Coronary Syndromes

- All patients with non-ST-segment-elevation acute coronary syndromes (NSTEACS) should have their risk stratified to direct management decisions (see page 20 in the original guideline document for stratification criteria).
- All patients with NSTEACS should be given aspirin, unless contraindicated.
- High-risk patients with NSTEACS should be treated with aggressive medical management (including aspirin, clopidogrel, unfractionated heparin or subcutaneous enoxaparin, intravenous tirofiban or eptifibatide and a beta-blocker), and arrangements should be made for coronary angiography and revascularisation, except in those with severe comorbidities.
- Intermediate-risk patients with NSTEACS should undergo an accelerated diagnostic evaluation and further assessment to allow reclassification as low or high risk.
- Low-risk patients with NSTEACS, after an appropriate period of observation and assessment, may be discharged on upgraded medical therapy for outpatient follow up.

Long-term Management after Control of Myocardial Ischaemia

- Before discharge, patients with an ACS should be initiated on a medication regimen, including antiplatelet agent(s), beta-blocker, angiotensin-converting enzyme inhibitor, statin, and other therapies as appropriate.
- Implantable cardiac defibrillators should be considered in some patients who, despite optimal medical therapy, have persistently depressed left ventricular function more than 6 weeks after STEMI.
- Patients should be given advice on lifestyle changes that will reduce the risk of further coronary heart disease (CHD) events, including smoking cessation, nutrition, alcohol, physical activity, and weight management as relevant.
- All patients should have access to, and be actively referred to, comprehensive ongoing prevention and cardiac rehabilitation services.
- All patients should be provided with a written action plan for chest pain.
- Depression and CHD frequently coexist, and in patients with CHD, the presence of depression is more likely to lead to poorer outcomes. Social isolation and lack of social support are also associated with worse outcomes. All patients with CHD should be assessed for depression and level of social support.

CLINICAL ALGORITHM(S)

Clinical algorithms are provided in the original guideline document for the following:

- Defining acute coronary syndromes over time: presentation to final diagnosis
- Hospital management of ST-segment-elevation myocardial infarction (STEMI)
- Prehospital management of STEMI
- Treatment strategies for patients with non-ST-segment elevation acute coronary syndromes (NSTEACS), based on risk stratification
- Implantable cardiac defibrillator (ICD) implantation after STEMI: proposed management

- Emergency department/cardiac care unit (CCU) guidelines for the management of acute coronary syndromes

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type evidence supporting the recommendations is specifically stated for selected recommendations in the original guideline document.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis and appropriate management of acute coronary syndromes

POTENTIAL HARMS

- Enoxaparin may be used in conjunction with fibrin-specific fibrinolytic agents, but care should be taken in patients who are aged over 75 years or who have renal dysfunction, as dose adjustment is necessary.
- Full-dose glycoprotein (GP) IIb/IIIa inhibitors should be avoided with fibrinolytic therapy as there is evidence of excessive bleeding (including intracranial haemorrhage) with this combination.
- Streptokinase should not be given to patients with previous exposure (more than 5 days ago) to the drug. There is also evidence that streptokinase may be less effective in Aboriginal and Torres Strait Islander peoples because of the high levels of skin infection (and thus streptococcal antibodies), particularly in remote populations.
- Side effects associated with streptokinase include hypotension and allergy.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications and Cautions for Fibrinolysis use in ST-segment-elevation Myocardial Infarction

Absolute Contraindications

Risk of Bleeding

- Active bleeding or bleeding diathesis (excluding menses)
- Significant closed head or facial trauma within 3 months
- Suspected aortic dissection (including new neurological symptoms)

Risk of Intracranial Haemorrhage

- Any prior intracranial haemorrhage

- Ischaemic stroke within 3 months
- Known structural cerebral vascular lesion (e.g., arteriovenous malformation)
- Known malignant intracranial neoplasm (primary or metastatic)

Relative Contraindications

Risk of Bleeding

- Current use of anticoagulants: the higher the international normalised ratio (INR), the higher the risk of bleeding
- Non-compressible vascular punctures
- Recent major surgery (<3 weeks)
- Traumatic or prolonged (>10 minutes) cardiopulmonary resuscitation
- Recent (within 4 weeks) internal bleeding (e.g., gastrointestinal or urinary tract haemorrhage)
- Active peptic ulcer

Risk of Intracranial Haemorrhage

- History of chronic, severe, poorly controlled hypertension
- Severe uncontrolled hypertension on presentation (>180 mmHg systolic or > 110mmHg diastolic)
- Ischaemic stroke more than 3 months ago, dementia, or known intracranial abnormality not covered in contraindications

Other

Pregnancy

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines were developed by means of a consensus approach which involved an independent assessment of key Australian and international evidence-based clinical guidelines, scientific articles and trial data, which are incomplete in some areas.
- Recommendations are not necessarily congruent with current Pharmaceutical Benefits Scheme criteria for eligibility for subsidy in all areas.
- The guidelines provide a general framework for appropriate practice, to be followed subject to the practitioner's judgement in each individual case. All treatments should be individualised according to the patient's comorbidities, drug tolerance, lifestyle and living circumstances, and wishes.
- For all medications, observe usual contraindications, be mindful of the potential for significant and possibly adverse drug interactions and allergies, and monitor and review patients carefully and regularly.
- Where drug therapy is recommended for indefinite use, these recommendations have been based on the extrapolated findings of clinical trials which are by their nature of limited duration.
- The guidelines are designed to provide information to assist decision making, and are based on the best information available up to September 2005. It

should be understood that the context in which clinical trials are performed and the local environment in which practice is undertaken must always be considered when assessing the evidence base for guidelines and, at times, their local implementation.
- The information in these guidelines has been independently researched and developed by the National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand, and is based on scientific evidence. It is not an endorsement of any particular company, product or service.
- This document has been produced by the National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand for the information of health professionals. The statements and recommendations it contains are, unless labeled as "expert opinion", based on independent review of the available evidence. Interpretation of this document by those without appropriate medical and/or clinical training is not recommended, other than at the request of, or in consultation with, a relevant health professional.
- While care has been taken in preparing the enclosed information, the National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand and their employees cannot accept any liability, including for any loss or damage resulting from the reliance on the information, or for the accuracy, currency or completeness of the information.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Quick Reference Guides/Physician Guides
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Acute Coronary Syndrome Guidelines Working Group. Guidelines for the management of acute coronary syndromes 2006. Med J Aust 2006 Apr 17;184(8 Suppl):S1-32. [105 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Apr

GUIDELINE DEVELOPER(S)

Cardiac Society of Australia and New Zealand - Disease Specific Society
National Heart Foundation of Australia - Disease Specific Society

SOURCE(S) OF FUNDING

National Heart Foundation of Australia
Cardiac Society of Australia and New Zealand

GUIDELINE COMMITTEE

Acute Coronary Syndrome Guidelines Working Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The following working group members are consultants, advisory committee members, or receive honoraria, fees for service, or travel assistance (independent of research related meetings) from, or have research or other associations with the organisations listed: Roger Allan—Merck Sharpe & Dohme, Sanofi; Con Aroney—CSL, Merck Sharpe & Dohme, Sanofi-aventis; Phil Aylward—Sanofiaventis, Pfizer, Merck, Bristol-Myers Squibb, Boehringer Ingelheim, AstraZeneca, Procter & Gamble, Eli Lilly, The Medicines Co, Servier, CSL, Schering Plough; David Brieger—Aventis, Sanofi, Boehringer Ingelheim, Merck Sharpe & Dohme; Alex Brown—National Heart Foundation of Australia, Australian Indigenous Doctors' Association, Alice Springs Hospital Management Board, Bristol-Myers Squibb, Pfizer; Gerard Carroll—Aventis, Bristol-Myers Squibb, AstraZeneca, Merck Sharpe & Dohme, Servier, Solvay, Roche; Derek Chew—Merck Sharpe & Dohme, Sanofi, Pfizer; Ian Jacobs—St John Ambulance, Australian Government Department of Health and Ageing, Convention of Ambulance Authorities Australia, National Health and Medical Research Council, Laerdal Foundation, National Heart Foundation of Australia, Health Department of Western Australia; Anne-Maree Kelly—Proctor & Gamble/Alexion, Boehringer Ingelheim; Shiong Tan—Health Department of Western Australia (Office of Safety & Quality and Sentinel event review group), Royal Australian College of General Practitioners (Quality Care National Standing Committee), National Prescribing Service (Director), Royal Australian College of General Practitioners (WA) Faculty (Director); Andrew Tonkin—Astra-Zeneca, Bristol-Myers Squibb, Pfizer, Sankyo, Fournier, Servier, Merck Sharpe & Dohme; Warren Walsh—Roche; Harvey White—The Medicines Company, AstraZeneca, Aventis, Bayer, Boehringer Ingelheim, Eli Lilly, Merck Sharpe & Dohme, Novartis, Pfizer, Roche, Servier, Wyeth Ayerst

ENDORSER(S)

Australian Cardiac Rehabilitation Association - Professional Association
Australian College for Emergency Medicine - Medical Specialty Society
Australian Indigenous Doctors Association - Professional Association
Australian Resuscitation Council - Professional Association
Council of Ambulance Authorities (Australia) - Professional Association
Council of Remote Area Nurses of Australia Inc. - Professional Association
Internal Medicine Society of Australia and New Zealand - Medical Specialty Society
Kidney Health Australia - Professional Association
National Aboriginal Community Controlled Health Organisation - National Government Agency [Non-U.S.]
Royal Australian College of General Practitioners - Professional Association
Royal College of Nursing Australia - Professional Association

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Heart Foundation of Australia.

Print copies: Available from the National Heart Foundation of Australia's national telephone information service at 1300 36 27 87 or E-mail: heartline@heartfoundation.com.au.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidelines for the management of acute coronary syndromes 2006. Summary of key recommendations. 2006. 4 p. Electronic copies: Available in Portable Document Format (PDF) from the National Heart Foundation of Australia Web site.
- Emergency department/CCU guidelines for the management of acute coronary syndromes. ACS therapy algorithm. 2006 Apr. 1 p. Electronic copies: Available in Portable Document Format (PDF) from the National Heart Foundation of Australia Web site.
- Slide presentation - ACS Guidelines key recommendations . 2007. Available in Portable Document Format (PDF) from the National Heart Foundation of Australia Web site.

Print copies: Available from the National Heart Foundation of Australia's national telephone information service at 1300 36 27 87 or E-mail: heartline@heartfoundation.com.au.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 6, 2007. The information was verified by the guideline developer on June 27, 2007. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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